

1 on.

2 MR. MORIARTY: My objection on July  
3 11th, 2011, is that this is irrelevant and by the time  
4 of trial I expect that this will not come in under the  
5 Daubert challenge that we are going to make.

6 MS. DONAHUE: Join. Same objection,  
7 same reasons.

8 MR. MORIARTY: And I may have other  
9 bases, so I don't waive the argument on those.

10 BY MR. ERNST:

11 Q. Doctor, the 3.6 testing level that  
12 you've done is true and accurate; true?

13 A. According to the records I reviewed,  
14 that is the level that we -- we measured in the  
15 sample.

16 MR. MORIARTY: Objection. Move to  
17 strike as repetitive.

18 BY MR. ERNST:

19 Q. From a clinical standpoint, it is  
20 generally accepted -- and I believe you testified to  
21 this -- that in a living individual, digoxin  
22 therapeutic levels range from 0.5 to 0.20, and there  
23 are occasions where you've said it goes as high as  
24 2.5.

25 MS. DONAHUE: Objection.

1 MR. MORIARTY: Objection.

2 THE WITNESS: The therapeutic -- the  
3 therapeutic range is between 0.5 and 2.0 nanograms per  
4 mL. In some references it's up to 2.5 nanograms per  
5 mL.

6 In the older literature -- and this goes  
7 back decades now -- the level -- the therapeutic level  
8 is actually up to 4.0 nanograms per mL.

9 BY MR. ERNST:

10 Q. Now, are you aware that there was a  
11 recall of Digitek?

12 A. I was aware of that.

13 Q. And how did you become aware of the  
14 recall of -- for Digitek?

15 MR. MORIARTY: Objection.

16 MS. DONAHUE: Join.

17 THE WITNESS: I found out through a  
18 discussion with NMS that we were doing sampling of  
19 tablets from various manufacturers in which there was  
20 a recall.

21 MS. DONAHUE: Objection. Move to  
22 strike.

23 BY MR. ERNST:

24 Q. And did you ever sample any medication  
25 provided to you by Actavis?

1           A.           When you talk -- when you say "you," me  
2 personally?

3           Q.           The firm, NMS.

4           A.           I don't -- well, other than what was  
5 provided in this case, which I don't know the actual  
6 source of the medication, I can't answer that question  
7 because I don't know that.

8           Q.           Do you know if any work was done testing  
9 Digitek tablets by Mylan?

10          A.           I don't know that.

11                       MR. ERNST: Our next in order, is it  
12 20?

13                       COURT REPORTER: Yes.

14                       (Exhibit Barbieri-20 was marked for  
15 identification.)

16 BY MR. ERNST:

17          Q.           I'm going to mark as Exhibit 20 a  
18 two-page document that are referred to as a recall.

19                       Do you see that?

20                       MR. MORIARTY: May I see it, please?

21                       THE WITNESS: Yes.

22                       MR. MORIARTY: (Attorney reviews  
23 document.)

24 BY MR. ERNST:

25          Q.           Do you see that?

1 A. I have it.

2 Q. And do you see that according to Exhibit  
3 20 that the Digitek tablets, 0.25, were recalled as a,  
4 quote, precaution because the tablets may be double  
5 the appropriate thickness and could contain twice the  
6 approved level of active ingredient?

7 Do you see that?

8 MS. DONAHUE: Objection.

9 MR. MORIARTY: Objection.

10 THE WITNESS: I see that statement.

11 BY MR. ERNST:

12 Q. That is your understanding of why  
13 Digitek was recalled.

14 MS. DONAHUE: Objection.

15 MR. MORIARTY: Objection.

16 THE WITNESS: No.

17 BY MR. ERNST:

18 Q. What is your understanding of why  
19 Digitek was recalled?

20 A. I don't know. I just know that Digitek  
21 or products of generic -- excuse me -- products of  
22 generic digoxin, there was a recall involved and that  
23 NMS was doing some testing on some of those tablets.

24 The reason, I do not know. And I did  
25 not know at that time. And I do not know today.

1 Q. I want you to assume a couple of things  
2 here. I'm going to ask you some more questions.

3 I want you to assume that the coroner,  
4 Dr. Mason, sliced and cut the axillary vein of the arm  
5 and grabbed the arm by the wrist and ran his hand down  
6 the arm, squeezing the blood out of the arm for his  
7 test.

8 If you assume that is true, would that  
9 be peripheral blood?

10 MR. MORIARTY: Objection.

11 MS. DONAHUE: Objection.

12 THE WITNESS: That would be considered a  
13 peripheral blood sample.

14 BY MR. ERNST:

15 Q. And is it your understanding that  
16 peripheral blood samples have significantly less  
17 postmortem redistribution than heart samples?

18 MR. MORIARTY: Objection.

19 MS. DONAHUE: Objection.

20 THE WITNESS: For digoxin?

21 BY MR. ERNST:

22 Q. Yes.

23 A. Yes.

24 Q. Now, I want you to assume that  
25 Mr. McCornack was 45 years old, that he was taking

1 digoxin through a prescribed Digitek, and that his  
2 steady state was 1.6. Okay?

3 A. Uh-huh.

4 Q. Is that a yes?

5 A. That's a yes.

6 Q. Now --

7 A. And his last test was done, again, in  
8 2007, you said?

9 Q. Eleven months prior.

10 A. Okay.

11 Q. But his history was consistent and had  
12 been consistent at that blood level at or near for ten  
13 years.

14 A. Okay.

15 Q. And I want you to assume that he then  
16 ingested one or more tablets in the days -- day  
17 immediately before his death of a double strength  
18 tablet of Digitek.

19 A. We're assuming it's a double strength?  
20 That's what you want me to assume?

21 Q. Assuming. Assuming.

22 A. Okay.

23 Q. Would his postmortem blood level -- or  
24 is a postmortem blood level of 3.6 consistent with  
25 that?

1 MS. DONAHUE: Objection.

2 MR. MORIARTY: Objection.

3 THE WITNESS: It may be, but digoxin  
4 kinetics in terms of blood levels are not linear. So  
5 that just by doubling the dose does not mean that  
6 you're going to double the circulating blood level in  
7 a living person.

8 BY MR. ERNST:

9 Q. True.

10 My question -- that's what your  
11 testimony is. But my question is, is it consistent?

12 In other words, if you assume those  
13 facts to be true, that he had been stable at 1.6 and  
14 he's exposed to double strength tablets, that, in  
15 fact, a blood -- a postmortem sample of 3.6 would be  
16 consistent with that?

17 A. It's possible but --

18 MS. DONAHUE: Objection.

19 THE WITNESS: -- it's not -- it's not  
20 definitive.

21 MR. MORIARTY: Objection. Motion to  
22 strike.

23 BY MR. ERNST:

24 Q. It's not inconsistent, is it, Doctor?

25 MS. DONAHUE: Objection.

1 MR. MORIARTY: Objection.

2 THE WITNESS: I'd have to give the same  
3 answer.

4 BY MR. ERNST:

5 Q. Now, NMS usually runs tests if asked to  
6 do it for digoxin; correct?

7 MS. DONAHUE: Objection.

8 THE WITNESS: Yes.

9 BY MR. ERNST:

10 Q. And the reason they run that test is  
11 why?

12 A. The purpose of it is for -- well, there  
13 are various purposes. One of them is for digoxin  
14 toxicity on biological samples.

15 Another purpose of the test is to help  
16 agencies or clients who are producing standards of  
17 digoxin for sale to verify their concentration.

18 It could be for various other types of  
19 forensic purposes.

20 Q. To your knowledge, has NMS ever tested  
21 any of Actavis' drugs before the recall?

22 A. I don't know the answer to that. I  
23 can't answer that.

24 Q. Who would know?

25 A. Probably somebody in the R & D group.



1 Matt McMullin would probably be the best one to answer  
2 that question.

3 Q. Now, if I go back and ask you a couple  
4 of more hypothetical questions -- well, first of all,  
5 let's go back and talk about the literature.

6 Counsel has asked you a whole host of  
7 questions about literature. He's given you 19  
8 different articles. And many of the articles are  
9 about not digoxin, but other drugs; true?

10 A. Yes.

11 MS. DONAHUE: Objection.

12 BY MR. ERNST:

13 Q. And, in fact, many of the articles --  
14 and you were asked to pull out a particular sentence  
15 here or there -- some had to do with the studies of  
16 children.

17 A. There was one that I saw, yes. I think  
18 that was the Koren article.

19 Q. And some of them -- some of the specific  
20 items that were pulled out you might agree with.

21 A. Yes.

22 Q. And some you disagreed with.

23 A. Yes.

24 Q. What you can say is that the blood level  
25 that you tested Mr. McCornack for at the time you were

1 requested to do so, the level came back at 3.6.

2 A. That's correct.

3 Q. And the therapeutic, generally accepted  
4 value in the United States today is 0.5 to 2.0.

5 MS. DONAHUE: Objection.

6 BY MR. ERNST:

7 Q. Is that accurate?

8 A. In antemortem, plasma, or serum samples,  
9 yes.

10 Q. Yes.

11 Now, I want to talk about peripheral  
12 blood, and you mentioned being able to ballpark  
13 whether or not there's a great deal or not much of  
14 postmortem redistribution with peripheral blood.

15 MS. DONAHUE: Objection.

16 BY MR. ERNST:

17 Q. Do you have any thoughts on postmortem  
18 redistribution of peripheral blood?

19 MR. MORIARTY: Objection.

20 MS. DONAHUE: Objection.

21 THE WITNESS: For digoxin specifically?

22 BY MR. ERNST:

23 Q. Yes. Yes.

24 A. There is postmortem redistribution  
25 associated with peripheral blood for digoxin.

1 Q. It is much less than around the heart.

2 MS. DONAHUE: Objection.

3 MR. MORIARTY: Objection.

4 THE WITNESS: Absolutely.

5 And, of course, any postmortem  
6 redistribution is time dependent as well.

7 BY MR. ERNST:

8 Q. Now, when you say "time dependent," in  
9 other words, you want the sample taken as promptly as  
10 you can after death.

11 A. Yes.

12 Q. Now, you're aware how coroners' offices  
13 work across the United States.

14 A. Many of them.

15 Q. Sometimes you can get three days,  
16 sometimes you can get as late as I think you testified  
17 ten days.

18 MS. DONAHUE: Objection.

19 THE WITNESS: It's possible -- I think I  
20 said a week, but it's possible, yes.

21 BY MR. ERNST:

22 Q. Now, in this particular case, having  
23 marked Exhibit 20, if you assume that the recall came  
24 out May 2nd, 2008, that would have been some five  
25 weeks after the death of Mr. McCornack.

1 A. Okay.

2 Q. True?

3 A. If the calculation is correct, okay.

4 Q. Now --

5 A. That's not when the sample was taken.

6 That's when the recall came out after his death.

7 Q. Right.

8 A. Okay.

9 Q. As a scientist, if you had known about a  
10 recall, you would have wanted to do a host more tests;  
11 right?

12 MR. MORIARTY: Objection.

13 MS. DONAHUE: Objection.

14 THE WITNESS: No. We're not -- we're  
15 not in the business of testing products for recalls.  
16 We're in the business of testing requests for a  
17 particular compound for a client for whatever purpose  
18 they deem appropriate.

19 BY MR. ERNST:

20 Q. So today, at -- in your position, what  
21 you can testify about is that the blood level of 3.6  
22 is accurate as far as the testing procedure that you  
23 utilized; true?

24 A. Yes.

25 MR. MORIARTY: Objection. Repetitive

1 times five.

2 BY MR. ERNST:

3 Q. And beyond that, beyond that, if you  
4 were to be asked to render an opinion assuming that he  
5 was 45, his kidney functions were normal, his weight  
6 was 200 pounds, he had been stable for ten years on  
7 Digitek at or about the 1.6 level, that he had been  
8 taking Digitek twice per day, once in the morning,  
9 once in the evening, that the taking of his medication  
10 was in an appropriate and compliant fashion, that he  
11 died approximately four and a half to six and a half  
12 hours after ingesting his last Digitek tablet, that  
13 the autopsy was done on March 26th, 2008, at  
14 7:30 a.m., that he died March 23rd at 12:52 a.m., that  
15 the blood was taken from a peripheral vein, that it  
16 was properly taken from a peripheral vein, a blood  
17 level of 3.6 is consistent with digoxin toxicity.

18 MS. DONAHUE: Objection.

19 MR. MORIARTY: Objection. Asked and  
20 answered.

21 THE WITNESS: And I think I stated  
22 previously, it's possible --

23 BY MR. ERNST:

24 Q. All right.

25 A. -- but not necessarily scientifically

1 always correct.

2 Q. You would defer to the coroner and you  
3 would defer to his treating physicians and you would  
4 defer to the people that had a clinical history of  
5 him; true?

6 MR. MORIARTY: Objection.

7 MS. DONAHUE: Objection.

8 THE WITNESS: In terms of what? The  
9 level?

10 BY MR. ERNST:

11 Q. In terms of his medical history, the  
12 level and combining all of the clinical symptomatology  
13 and material that is available to a person viewing the  
14 history and the testing of Mr. McCornack.

15 MR. MORIARTY: Objection.

16 MS. DONAHUE: Objection.

17 THE WITNESS: In terms of what decision,  
18 his cause of death?

19 What are you -- I'm agreeing to what?  
20 What's the fact?

21 BY MR. ERNST:

22 Q. You are -- you would defer any opinion  
23 as to the cause of death to a physician.

24 MR. MORIARTY: Objection.

25 MS. DONAHUE: Objection.

1 THE WITNESS: That had all those -- that  
2 information?

3 BY MR. ERNST:

4 Q. Yes.

5 A. I would.

6 MR. MORIARTY: Don --

7 VIDEO OPERATOR: Two-minute warning.  
8 Two minutes.

9 MR. ERNST: We'll change the tape.

10 VIDEO OPERATOR: We are going off the  
11 record at 1:59.

12 (A recess was taken from 1:59 to  
13 2:18 p.m.)

14 VIDEO OPERATOR: We're back on the  
15 record at 2:18.

16 You may continue.

17 BY MR. ERNST:

18 Q. Doctor, as long as you've been at NMS  
19 Laboratories there have been occasional requests for  
20 tests of digoxin postmortem; true?

21 A. Yes.

22 Q. And digoxin has a very narrow  
23 therapeutic range.

24 A. Yes.

25 Q. And while digoxin can help people, it

1 can also kill people.

2 A. Yes.

3 MR. MORIARTY: Objection.

4 BY MR. ERNST:

5 Q. And if there's a sudden increase in the  
6 level of digoxin to a patient that has a stable level,  
7 assuming 1.6 is his therapeutic steady-state level, a  
8 sudden increase in digoxin could have an effect of  
9 sudden death.

10 MS. DONAHUE: Objection.

11 MR. MORIARTY: Objection.

12 THE WITNESS: It's a possibility.

13 BY MR. ERNST:

14 Q. And, in fact, sudden death is an effect  
15 that digoxin toxicity causes based on your training  
16 and experience.

17 MS. DONAHUE: Objection.

18 THE WITNESS: That's one of the  
19 toxicities listed.

20 BY MR. ERNST:

21 Q. Because they've made an objection,  
22 please state for me the toxic results that one would  
23 expect to see, and the range, if there is digoxin  
24 toxicity.

25 MS. DONAHUE: Objection.



1 THE WITNESS: You mean a list of the  
2 toxic effects --

3 BY MR. ERNST:

4 Q. Yeah. Yeah.

5 One of them is sudden death.

6 A. Well --

7 MR. MORIARTY: Objection.

8 THE WITNESS: -- you can start out with  
9 the patient may experience nausea and vomiting.

10 BY MR. ERNST:

11 Q. That doesn't happen all the time, does  
12 it?

13 A. None of the --

14 MS. DONAHUE: Objection.

15 THE WITNESS: -- none of the things I'm  
16 going to mention happens all the time.

17 BY MR. ERNST:

18 Q. Okay. Let's just mention those things,  
19 the range, please.

20 A. There's -- patient-to-patient  
21 variability is very broad with a drug like digoxin.  
22 But some of the things that can happen: Nausea and  
23 vomiting can occur. There's a sudden change in  
24 vision, yellow halos may start to appear in the eyes.

25 In terms of the more serious toxicities,

1 the patient may start to get peripheral ventricular  
2 arrhythmias. They may throw an arrhythmia from the  
3 atria, so you have an atrial tachycardia that occurs.

4 Q. What does that mean --

5 A. That means --

6 Q. -- to a layperson?

7 A. That means that the atria, which is the  
8 top of the heart, begins to beat abnormally. The  
9 ventricle is still beating normally.

10 Atrial tachycardia or paroxysmal, it's  
11 called, atrial tachycardia, which means it can occur  
12 suddenly, can then -- if not treated and handled, can  
13 then generate ventricular arrhythmias so that the  
14 ventricles are beating in an abnormal fashion. That's  
15 more life threatening.

16 You can end up with ventricular  
17 tachycardia, which means an increasing heart rate,  
18 going to ventricular fibrillation, which means that  
19 the muscle is not beating and pumping blood, it's  
20 just -- it's just kind of squirming around, and then  
21 you could have sudden death from stoppage of heart  
22 beating.

23 So all of these are progressive events  
24 that can occur as digoxin toxicity occurs in the  
25 heart.

1 MS. DONAHUE: Objection. Move to  
2 strike.

3 BY MR. ERNST:

4 Q. If a person is sleeping and took more  
5 digoxin -- ingested more digoxin than was normally  
6 taken, could ventricular fibrillation occur while one  
7 is asleep?

8 MR. MORIARTY: Objection.

9 MS. DONAHUE: Objection.

10 THE WITNESS: Yes.

11 BY MR. ERNST:

12 Q. What happens in that case?

13 A. Ventricular fibrillation?

14 Q. Yes.

15 A. The heart is not --

16 MS. DONAHUE: Objection.

17 THE WITNESS: The heart is not pumping  
18 blood.

19 BY MR. ERNST:

20 Q. A person goes to sleep and just doesn't  
21 wake up?

22 A. Well, the heart is not pumping blood and  
23 so they may -- they may awaken gasping for breath  
24 because they're not getting oxygen, or they may die  
25 suddenly in their sleep. Again, variability depending

1 upon the person.

2 Q. But one of the side effects of digoxin  
3 toxicity would be a person waking up from sleep or  
4 gasping for breath.

5 A. That's --

6 MS. DONAHUE: Objection.

7 THE WITNESS: -- that is possible.

8 BY MR. ERNST:

9 Q. It's also possible that sudden death  
10 could occur.

11 MS. DONAHUE: Objection.

12 MR. MORIARTY: Objection.

13 THE WITNESS: That's possible.

14 BY MR. ERNST:

15 Q. It's also possible that a person could  
16 become -- vomiting -- start vomiting, nauseous.

17 A. Yes.

18 MS. DONAHUE: Objection.

19 BY MR. ERNST:

20 Q. And is it -- I think you testified that  
21 any one of these symptoms could occur in the case of  
22 digoxin toxicity.

23 MR. MORIARTY: Objection.

24 MS. DONAHUE: Objection.

25 THE WITNESS: All are possible and any

1 or all could occur.

2 BY MR. ERNST:

3 Q. Now, how does sudden death occur in a  
4 case of digoxin toxicity?

5 MR. MORIARTY: Objection.

6 THE WITNESS: Well, it's basically  
7 really not sudden death because you go through this  
8 pattern of paroxysmal atrial tachycardia, ventricular  
9 tachycardia, ventricular fibrillation means that the  
10 heart stops, but the patient is not aware of that.

11 So they present as though they die  
12 suddenly, but actually all of those things probably  
13 occurred. The patient just doesn't realize that the  
14 -- when the atria are beating quickly, you don't feel  
15 it.

16 Ventricular tachycardia you tend to  
17 feel. But if they're not sensitive to it, they may  
18 not realize it. And so it progresses to a point where  
19 the heart stops beating.

20 MS. DONAHUE: Objection. Move to  
21 strike.

22 BY MR. ERNST:

23 Q. Now, you have just testified as the  
24 basis -- on the basis of a toxicologist; true?

25 A. Yes.

1 Q. And you feel comfortable and adequate to  
2 render those opinions.

3 A. They're not opinions, they're facts in  
4 terms of the effects of digoxin.

5 Q. From what I hear you saying, if a person  
6 who was fatigued or is sweating, would that be a side  
7 effect that one would expect?

8 MR. MORIARTY: Objection.

9 MS. DONAHUE: Objection.

10 THE WITNESS: That's not common.

11 BY MR. ERNST:

12 Q. If one experienced digoxin toxicity, you  
13 have mentioned a host of things. I'll list them:  
14 vomiting, change in vision, yellow halos, the  
15 ventricular fibrillation of which they would not be  
16 aware of, and sudden death.

17 A. Yes.

18 Q. Now, if a person went to bed and had  
19 digoxin toxicity, they might just die or they might be  
20 gasping for breath. That's one of the possibilities;  
21 true?

22 A. Yes.

23 MS. DONAHUE: Objection.

24 MR. MORIARTY: Objection.

25 THE WITNESS: It's possible.

1                   And they may survive these.

2   BY MR. ERNST:

3           Q.       And they may die.

4                   MS. DONAHUE:  Objection.

5                   THE WITNESS:  Either way.

6   BY MR. ERNST:

7           Q.       Is that one of the reasons that NMS  
8   performs tests on postmortem blood samples looking for  
9   digoxin toxicity?

10          A.       No.

11          Q.       NMS performs tests postmortem because  
12   they are asked to do so?

13          A.       Yes.

14          Q.       And they are asked to do so by coroners  
15   from across the United States.

16          A.       By coroners, medical examiners, police  
17   agencies, district attorneys, drug companies, lab --  
18   other laboratories to verify their results.  There are  
19   many reasons, many types of clients.

20          Q.       When you get a request to test for  
21   digoxin in postmortem blood, you don't ask why, you  
22   just perform the test.

23          A.       Yes.

24          Q.       And in this case, Exhibit 8 are the  
25   results of that test that you were asked to perform.

1 A. Yes.

2 Q. And I take it that Exhibit 8 and the  
3 results of a digoxin test are what you as a  
4 toxicologist would expect coroners and treating  
5 doctors to rely upon as one factor in an overall  
6 picture in rendering an opinion.

7 MR. MORIARTY: Objection.

8 MS. DONAHUE: Objection.

9 THE WITNESS: I would agree. That's  
10 information like any other type of information in a  
11 particular case.

12 BY MR. ERNST:

13 Q. Doctor, to you as a toxicologist, that  
14 3.6 number is relevant, isn't it, to you?

15 A. Well, as I said before, it's not  
16 insignificant.

17 Any -- any digoxin concentration is not  
18 insignificant. And a 3.6 again is not insignificant.

19 So it's something to look at and say,  
20 here we have a digoxin, a confirmed identification,  
21 and we have a quantification.

22 Q. In fact, you would expect that another  
23 physician either treating, or a coroner, would take  
24 that number and factor it into his or her opinion to  
25 determine a cause of death.



1 MR. MORIARTY: Objection.

2 THE WITNESS: Well, we may expect that.

3 We don't know if that happens.

4 BY MR. ERNST:

5 Q. Right.

6 You just produce the number.

7 A. We produce the number. I mean, we would  
8 -- we would like to say that, you know, everybody at  
9 the other end understands what we're doing, what that  
10 number means, but we don't know. Many times we don't  
11 know.

12 Q. Now, you have testified about the  
13 peripheral blood and how important it is to you for  
14 peripheral blood as opposed to heart blood.

15 A. Okay.

16 Q. And if I were to describe for you how  
17 the coroner took the blood in this case, and by his  
18 own testimony stated, Normally you grab the arm by the  
19 wrist and run your hand down the arm and squeeze the  
20 juice out of there, that would be peripheral blood  
21 sample; true?

22 A. And I answered that question before. I  
23 would consider that, as that description would be,  
24 peripheral blood.

25 Q. Now, the fact that a coroner has

1 determined that there is -- based upon all of the  
2 records that were reviewed, all of the previous tests  
3 that were done for digoxin, a review of the recall  
4 notice, all of those materials, you would defer to the  
5 coroner and the treating physicians for their opinions  
6 as to the cause of death.

7 MR. MORIARTY: Objection.

8 THE WITNESS: Well, I'm not really  
9 deferring because I'm not giving an opinion. I mean,  
10 I wouldn't question that opinion because they have  
11 that information that we don't have or I don't have in  
12 this case or other cases.

13 So it's really not deferring. It's  
14 allowing them to do their job.

15 BY MR. ERNST:

16 Q. And based on your training and  
17 experience, the person whose job to determine the  
18 cause of death is the coroner?

19 A. The coroner, the medical examiner in the  
20 particular case, that's correct.

21 Q. Now, I want to talk for a moment, if I  
22 can, about some of the literature that has been  
23 presented to you today. There's been a whole host of  
24 things.

25 You were asked specific questions about

1 a sentence here or there; true?

2 A. Yes.

3 MR. MORIARTY: Objection.

4 MS. DONAHUE: Objection.

5 MR. MORIARTY: Asked and answered.

6 BY MR. ERNST:

7 Q. And after all of that questioning that  
8 was done by Mr. Moriarty, the number that you have,  
9 3.6, that was referred to the coroner is a number that  
10 you feel is accurate.

11 MR. MORIARTY: Objection. Asked and  
12 answered --

13 MS. DONAHUE: Objection. Asked and  
14 answered.

15 MR. MORIARTY: -- six times.

16 THE WITNESS: Yes.

17 BY MR. ERNST:

18 Q. And it is something that you would  
19 expect -- despite what all of this information and all  
20 of the questioning to you about whether or not  
21 postmortem blood can or cannot be determined to a  
22 specific level previously, it is a factor that you as  
23 a toxicologist would consider if you had all of the  
24 information and were asked to render an opinion.

25 MR. MORIARTY: Objection.

1 MS. DONAHUE: Objection.

2 THE WITNESS: I would.

3 BY MR. ERNST:

4 Q. As a toxicologist, would it be important  
5 to you to know that this particular patient, Dan  
6 McCornack, had had a consistent level between 1.5 and  
7 1.6 for the previous ten years?

8 MS. DONAHUE: Objection.

9 MR. MORIARTY: Objection.

10 THE WITNESS: It's information, but, of  
11 course, it's not in any way information that is  
12 applicable to what happened months later.

13 It's part of the medical history that we  
14 look at and we would consider, but not in terms of  
15 acting upon or making opinion as to what this number  
16 means or refers to in the case.

17 BY MR. ERNST:

18 Q. Going back to Mr. McCornack and his  
19 blood level, if I were to ask you to assume that  
20 Mr. McCornack had purchased Digitek tablets that were  
21 recalled after his death and that he had properly  
22 taken Digitek tablets that were recalled after his  
23 death in the 0.25 milligram range, that he had  
24 appropriately taken those tablets and had been exposed  
25 to double strength tablets and had ingested them,

1 would a blood level postmortem of 3.6 be consistent  
2 with ingesting double strength tablets?

3 MR. MORIARTY: Objection.

4 MS. DONAHUE: Objection.

5 THE WITNESS: And I think I answered the  
6 question before, and I'll answer it again, it's  
7 possible.

8 BY MR. ERNST:

9 Q. Doctor --

10 MR. ERNST: I'd just like to go off the  
11 record for a moment.

12 VIDEO OPERATOR: We're going off the  
13 record at 2:34.

14 (Discussion off the record.)

15 VIDEO OPERATOR: We're back on the  
16 record at 2:37.

17 BY MR. ERNST:

18 Q. Before I asked you these questions,  
19 Mr. Moriarty asked you a whole host of questions on 20  
20 different items in the literature.

21 Have any of those items changed or  
22 modified your thought process or what you've just  
23 testified to in any way?

24 A. No.

25 MS. DONAHUE: Objection.

1 MR. ERNST: No other questions.

2 MR. MORIARTY: Do you want to ask your  
3 one question?

4 MS. DONAHUE: No, you can go ahead.

5 EXAMINATION

6 BY MR. MORIARTY:

7 Q. Okay. Mr. Ernst started his examination  
8 by talking to you about these discussions about the  
9 scope of your anticipated testimony; right?

10 A. Yes.

11 Q. All of those discussions took place  
12 after May 15th; right?

13 A. Yes.

14 Q. All those discussions took place after  
15 the ball got going on scheduling this deposition when  
16 we first started talking about it in June; correct?

17 A. Well, the first discussion was on May  
18 27th. I don't think we scheduled this deposition  
19 until after that.

20 Q. No, but the first discussions that you  
21 had with Mr. Ernst about the scope of your testimony  
22 and the opinions you would render or not took place  
23 much later; correct?

24 A. It took place much later, but that was  
25 before we actually scheduled.

1 Q. Right.

2 A. Yes.

3 Q. Mr. Ernst asked you a hypothetical, and  
4 I counted at least 19 assumptions that he wanted you  
5 to make.

6 Do you remember that long hypothetical?

7 A. It was a long one.

8 Q. All right. You don't know whether --  
9 how many of those facts are true, do you?

10 A. No, I don't.

11 Q. Do you know anything at all about Dan  
12 McCornack's underlying cardiac condition?

13 A. Only from what Dr. -- the doctor put on  
14 the test requisition form, that he had some cardiac  
15 problems.

16 Q. Are you a -- in a position to testify  
17 about the degree to which Dan McCornack's heart  
18 conditions increased the risk of sudden cardiac death  
19 in him?

20 A. No, I'm not.

21 Q. Did you notice that Mr. Ernst's  
22 hypothetical asked you nothing about diltiazem?

23 A. Yes, that's true.

24 Q. That's a pretty significant fact in this  
25 case, isn't it?

1 A. It's a significant fact.

2 Q. Do you know anything about the medical  
3 significance of a recall --

4 A. Not --

5 Q. -- a product recall?

6 A. No, not specifically.

7 Q. Do you know anything about the legal  
8 significance of a product recall?

9 A. Again, not the legal issues, but I know  
10 it's not good.

11 Q. Do you know what FDA said in its -- on  
12 its website after this recall about the prospects of  
13 there being defective tablets harming patients?

14 A. No, I have no information.

15 Q. Do you take FDA recall notices into  
16 account in your typical daily practice as a forensic  
17 toxicologist?

18 A. No.

19 Q. And of the recalled tablets, the six  
20 that your company tested, they were all within the  
21 specs, weren't they?

22 MR. ERNST: Objection.

23 THE WITNESS: Yes.

24 BY MR. MORIARTY:

25 Q. And the 18th item in Mr. Ernst's



1 hypothetical, by my count, was something about the  
2 coroner changing his original autopsy diagnosis to  
3 reflect death because of digoxin toxicity.

4 Do you remember him saying that?

5 A. I do.

6 Q. And do you remember telling me several  
7 hours ago that knowing what you know about the  
8 circumstances surrounding this, you would not have  
9 advised him to change his opinion based on this 3.6?

10 A. Yes.

11 MR. ERNST: Object -- objection.

12 Incomplete.

13 BY MR. MORIARTY:

14 Q. Anything change your mind on that in the  
15 last hour?

16 MR. ERNST: Object -- objection.

17 THE WITNESS: No.

18 BY MR. MORIARTY:

19 Q. He then asked you some -- Mr. Ernst  
20 asked you some hypotheticals about a 1.6 steady  
21 state. I want to ask you about that.

22 Would you want to know how often  
23 Mr. McCornack had been tested over the years before  
24 deciding whether 1.6 was a steady state?

25 A. That would be important information.

1 Q. The fewer the times he was tested over  
2 the years, the less likely you would be to say that  
3 1.6 was his steady state; right?

4 A. Well, each -- each test, the further  
5 apart they were, it would have less significance in  
6 terms of actually being a steady state.

7 Q. And I think you said the 1.6 from May of  
8 2007 would not apply to his steady state in March of  
9 2008; right?

10 A. That's correct.

11 Q. Do you still agree with that?

12 A. Yes, I do.

13 Q. So to assume that he was steady state  
14 1.6 is a poor assumption; correct?

15 MR. ERNST: Objection.

16 THE WITNESS: Based on the way it was  
17 presented, it really has no significance to what  
18 happened around March 2008.

19 BY MR. MORIARTY:

20 Q. Okay. Now, Mr. Ernst was talking about  
21 my use of the literature.

22 There is no one definitive medical  
23 article about postmortem analysis of digoxin; correct?

24 A. Correct.

25 Q. These things unfold over time as people

1 research and come to more understanding; is that  
2 right?

3 A. That's how science progresses, yes.

4 Q. And so you as a scientist -- and you've  
5 been doing this how many years?

6 A. Well, I've been a forensics toxicologist  
7 for 13, but I've been doing pharmacology for 35.

8 Q. All right. So slowly over time you add  
9 more articles and you add more information because the  
10 science evolves; correct?

11 A. Yes.

12 Q. All right. And you try to get as much  
13 of those pieces together so that you can figure out  
14 what that consensus and the weight of authority are  
15 today; right?

16 A. Yes.

17 Q. Now, you've never diagnosed anybody with  
18 digoxin toxicity in a clinical setting; correct?

19 A. No, I have not.

20 Q. You can't do that; right?

21 A. No.

22 MR. ERNST: He can't do that.

23 Is that your testimony?

24 MR. MORIARTY: That's what I just said.

25 BY MR. MORIARTY:

1 Q. But let me ask you about some of the  
2 questions that Mr. Ernst asked you about, the signs  
3 and symptoms of digoxin toxicity.

4 From your knowledge of the body of  
5 literature on digoxin and toxicity from digoxin, is it  
6 unlikely that someone will skip all the prodromal  
7 signs and symptoms and go straight to sudden cardiac  
8 death?

9 MR. ERNST: Objection. No foundation.

10 THE WITNESS: It's unlikely.

11 BY MR. MORIARTY:

12 Q. And Mr. Ernst was asking you about what  
13 the coroner and some of these other doctors from  
14 California should do with this 3.6 result.

15 Do you think they should interpret this  
16 3.6 consistent with the science and the literature?

17 MR. ERNST: Objection. It's  
18 argumentative.

19 THE WITNESS: I would hope that they  
20 would.

21 BY MR. MORIARTY:

22 Q. And if the coroner was not a specialist  
23 in postmortem toxicology, especially regarding  
24 digoxin, would you expect them to either consult with  
25 a toxicologist or read some literature about the

1 subject?

2 MR. ERNST: Objection.

3 BY MR. MORIARTY:

4 Q. Before coming to some interpretive  
5 conclusion regarding this number?

6 MR. ERNST: Objection.

7 THE WITNESS: A part of our service is  
8 to be available for consultation and discussion on any  
9 case.

10 And so, yes, I would expect them to  
11 either consult with us or consult with somebody else  
12 about something that they're unfamiliar with before  
13 making a decision.

14 BY MR. MORIARTY:

15 Q. Yeah. If, for example, they didn't feel  
16 like consulting you because you're all the way across  
17 the country, they could consult one of the local  
18 toxicologists with whom they have an affiliation.

19 MR. ERNST: Objection.

20 THE WITNESS: Of course.

21 BY MR. MORIARTY:

22 Q. And would you want them to put more  
23 weight on this postmortem level of 3.6 than reasonable  
24 science would support?

25 MR. ERNST: Objection.

1 THE WITNESS: Again, I would leave that  
2 up to them. I wouldn't want them to put any weight on  
3 anything unless they have researched it and understand  
4 it completely.

5 BY MR. MORIARTY:

6 Q. I'm asking whether you would want them  
7 to put more weight on it than the science supports.

8 MR. ERNST: Objection.

9 THE WITNESS: Oh, no, I would not.

10 BY MR. MORIARTY:

11 Q. All right. And I think the reason for  
12 that, if I may be so bold, after having read this  
13 literature and gone over some of it with you, is that  
14 the fear is that there will be a misinterpretation of  
15 the data and actually a wrong conclusion about the  
16 cause of death if you put too much weight on a  
17 postmortem blood digoxin level.

18 MR. ERNST: Objection.

19 BY MR. MORIARTY:

20 Q. Is that right?

21 MR. ERNST: Objection.

22 THE WITNESS: That would be a reasonable  
23 statement.

24 MR. MORIARTY: Thank you. I have  
25 nothing else.

1 EXAMINATION

2 BY MS. DONAHUE:

3 Q. I just have two questions, Doctor.

4 You testified that it was Dr. Mason that  
5 was the one who requested you to run the blood test on  
6 the -- for digoxin; right?

7 A. Well, it was the -- it was the office.  
8 I think -- I think the notes say Sergeant Burt was  
9 actually the phone contact who made the -- made the  
10 call, but it probably came from Dr. Mason.

11 Q. And did anyone in this case, including  
12 Mr. Ernst, tell you that Dr. Mason had been retained  
13 or had been sent a letter retaining him as an expert  
14 in this case between the time of his first report and  
15 the time of his supplemental amended report?

16 A. I have no --

17 MR. ERNST: Objection.

18 THE WITNESS: I have no knowledge of  
19 that.

20 BY MS. DONAHUE:

21 Q. You said that you are aware of how  
22 coroners' offices -- most coroners' offices generally  
23 work across the United States?

24 A. Well, I don't know if I said -- if I  
25 said most, many.

1 Q. Some.

2 A. Yes.

3 Q. Have you ever heard of a situation where  
4 a coroner changed his opinion re cause of death  
5 subsequent to being retained as an expert?

6 MR. ERNST: Objection.

7 THE WITNESS: I'm sure it happened. I  
8 can't think of a specific instance.

9 BY MS. DONAHUE:

10 Q. You've never had that experience working  
11 with a coroner, have you?

12 A. Not that I can recall, no.

13 MS. DONAHUE: That's all I have. Thank  
14 you.

15 EXAMINATION

16 BY MR. ERNST:

17 Q. Doctor, you're retained on occasion;  
18 right?

19 A. Yes.

20 Q. And when you're retained on occasion,  
21 does it affect what you do or say?

22 A. Hopefully not. Hopefully I take the  
23 science and, you know, the conclusions come from the  
24 science, whether it's a plaintiff or defendant.

25 I hope that, you know, I would give



1     them, either side that would hire me, the same report  
2     based on what I interpret.

3           Q.         And when we spoke on the phone after we  
4     sort of cleared the air, I asked you to be able to  
5     testify about the testing procedure that you've done,  
6     the 3.6, and what it would mean to you; true?

7           A.         Yes.

8           Q.         And after all of the testimony here and  
9     all of the statements that are made, the 3.6 blood  
10    level is important to you as a toxicologist because it  
11    is a factor that would be considered in the overall  
12    clinical picture of a cause of death; true?

13                   MR. MORIARTY:  Objection.

14                   MS. DONAHUE:  Objection.

15                   THE WITNESS:  Any drug that we have  
16    listed on a report, whether it's a low level or a high  
17    level, or even the presence of a compound, should be a  
18    factor to be considered.

19                   So the answer to your question would be  
20    yes.

21    BY MR. ERNST:

22           Q.         There were some questions mentioned  
23    about diltiazem.  And the diltiazem issue in your  
24    notes specifically states that regarding fatalities,  
25    postmortem blood concentrations range from 6,700 to

1 33,000.

2 Do you see that?

3 A. Yes.

4 Q. And when you look at the diltiazem level  
5 here, it's 630 nanograms.

6 A. Yes.

7 Q. It's not anywhere near that toxic level,  
8 is it?

9 A. No, it's not.

10 MR. ERNST: That's all I have.

11 MR. MORIARTY: May I see that, please.

12 (Attorney reviews document.)

13 EXAMINATION

14 BY MR. MORIARTY:

15 Q. Is there a universally known range of  
16 fatal numbers for diltiazem?

17 A. No.

18 Q. So it is theoretically possible that 630  
19 nanograms per milliliter could be fatal.

20 MR. ERNST: Objection.

21 BY MR. MORIARTY:

22 Q. In some case; right?

23 MR. ERNST: Objection.

24 THE WITNESS: Well, I guess it's  
25 theoretically possible. That would be highly

1 unlikely.

2 BY MR. MORIARTY:

3 Q. Okay. The fact is that it's three times  
4 the therapeutic level in the living, right, in this  
5 case?

6 A. If that was -- if that was an antemortem  
7 specimen, it would be three times.

8 Q. Yeah.

9 A. But, again, if you notice, we have a  
10 blood plasma ratio of about 2.6, I think.

11 Q. Okay.

12 A. This is the typical postmortem level  
13 that we see.

14 MR. MORIARTY: Okay. Thanks. That's  
15 all.

16 EXAMINATION

17 BY MR. ERNST:

18 Q. As the typical postmortem level that you  
19 see, you can relate that back; true?

20 A. Relate that back to what?

21 MR. MORIARTY: Objection.

22 MS. DONAHUE: Objection.

23 BY MR. ERNST:

24 Q. Relate it back to pre-serum level --

25 MS. DONAHUE: Objection.

1 BY MR. ERNST:

2 Q. -- or pre-death level.

3 A. No. Again, we've talked about that, and  
4 I'd like not to relate that back.

5 Q. I'm talking about diltiazem.

6 A. I understand. You have the same  
7 problems relating diltiazem back that we have to  
8 digoxin or any other drug.

9 Q. You'd want to refer to the total  
10 clinical picture.

11 A. Absolutely.

12 MR. ERNST: Thank you. That's all I  
13 have.

14 MR. MORIARTY: That's it.

15 VIDEO OPERATOR: This concludes the  
16 deposition of Dr. Barbieri. The time is 2:52.

17 MR. MORIARTY: Do you want to read and  
18 sign it or skip that?

19 THE WITNESS: I'll skip it.

20 MR. MORIARTY: He said he wants to not  
21 read and sign.

22 MR. ERNST: He's waiving signature.  
23 That's okay by me.

24 (Witness excused.)

25 (The deposition concluded at 2:53 p.m.)

## 1 CERTIFICATION

2  
3 I, DIANNA R. PUGLIESE, a Registered  
4 Merit Reporter, Certified Realtime Reporter and  
5 Commissioner of Deeds, hereby certify that the  
6 foregoing is a true and accurate transcript of the  
7 deposition of said witness who was first duly sworn by  
8 me on the date and place herein before set forth.

9 I FURTHER CERTIFY that I am neither  
10 attorney nor counsel for, not related to nor employed  
11 by any of the parties to the action in which this  
12 deposition was taken; and further that I am not a  
13 relative or employee of any attorney or counsel  
14 employed in this action, nor am I financially  
15 interested in this case.

16  
17  
18  
19 \_\_\_\_\_  
DIANNA R. PUGLIESE  
20 Registered Merit Reporter, Certified Realtime  
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